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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,848	10/02/2003	Neal M. Lonky	MEDT-01003US0	5129
23910	7590	05/26/2010	EXAMINER	
FLIESLER MEYER LLP 650 CALIFORNIA STREET 14TH FLOOR SAN FRANCISCO, CA 94108			HAND, MELANIE JO	
			ART UNIT	PAPER NUMBER
			3761	
			NOTIFICATION DATE	DELIVERY MODE
			05/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

OFFICEACTIONS@FDML.COM

Office Action Summary	Application No. 10/677,848	Applicant(s) LONKY, NEAL M.	
	Examiner MELANIE J. HAND	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7 and 15-26 is/are pending in the application.
- 4a) Of the above claim(s) 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,15-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 16, 2010 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 1, 3-7 and 15-26 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment to the claims.

Election/Restrictions

3. Newly submitted claims 24-26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 24-26 are directed to a kit for addressing flow of blood from a bleeding site. If these claims were presented originally with the examined method claims, a restriction requirement would have been made because the method can be practiced with a materially different product than the recited kit, e.g. a kit having a vacuum cup that does not have a cup lip.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

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on the merits. Accordingly, claims 24-26 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

4. The amendment filed April 16, 2010 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: All but paragraphs [0052]-[0055] contain at least one passage that introduces new matter. In paragraph [0045], there is no support in the disclosure as originally filed for an obstetric bonnet contoured to fit the fetal head. The specification only makes mention of applying a vacuum extractor in general terms to a fetal scalp. In paragraph 0046, the passage regarding reinforcement of the cup wall interior with an elastic mesh introduces new matter because no such reinforcement or reinforcement materials were disclosed originally. In paragraph 0047, the passage regarding a cup material manufactured purposely to leak introduces new matter. In paragraph 0048, no connection, integral or otherwise is disclosed originally therefore the entire paragraph introduces new matter. In paragraph 0049, the passage regarding a strain gauge introduces new matter, as no strain gauge was originally disclosed. In paragraph 0050, again no mechanical extensions were disclosed explicitly originally, therefore some of the extension examples, specifically a grommet, are not supported by the original disclosure. The rope, cord, etc. may be supported only if the mechanical extension in that case is the same as the tensioning structure that was originally disclosed. In paragraph 0051, none of the steps (1) – (6) were disclosed originally. In paragraphs 0056-0058, the passages regarding a check valve introduce new matter as no check valve was originally disclosed. It is for at least these reasons that the amendment to the

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specification introduces new matter. The applicant is strongly encouraged to review the new paragraphs for any additional material that is not clearly and explicitly supported by the original disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the disclosure as originally filed for a check valve. There is only support for a valve or a clamp, implying that the valve can be one-way or two-way.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. First, the claim recites "a method further comprising a check valve", wherein it is unclear what precise structural association or function the check valve has with the device employed in the method, if any. This prevents a proper prior art search of claim 20 by the

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examiner and therefore claim 20 cannot be further addressed herein with regard to 35 U.S.C. 102 or 35 U.S.C. 103. Second, claim 20 recites the limitation "the cup lip" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 3, 6, 7 and 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abboud (see attached PTO-892 form for full citation).

With respect to **claim 1**: Abboud discloses a method of slowing the flow of blood from a bodily tissue comprising: positioning the opening of a vacuum cup in the form of a suction box over the bleeding site (on the lower limb of a patient), wherein the vacuum cup/box includes an interior cavity; applying a vacuum to the interior cavity of the vacuum cup in a graded fashion so as to cause pooling of the blood flow; maintaining the vacuum until the flow of blood has slowed, detected by monitoring arterial baroreceptor activity.

Abboud discloses applying graded section only up to -40 mm Hg and discloses the monitoring of body response to the suction and its effect on blood flow to the bleeding site. Abboud discloses that the arterial baroreceptor reflex is invoked by excessive pooling caused by the amount of suction applied, and blood flow in the forearm slows as a result. Therefore while Abboud does not explicitly disclose the step of releasing the vacuum upon said slowing of blood

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flow in the forearm, Abboud certainly fairly suggests such a step of releasing the vacuum upon slowing the blood flow. It would therefore be obvious to one of ordinary skill in the art to modify the method of Abboud so as to include the step of releasing the vacuum upon slowing the blood flow with a reasonable expectation of success to prevent further reaction prompted by the arteriobaroreceptor reflex that may cause an undesired cardiac event. Though the step of removing the cup/box from the bleeding site after releasing the vacuum is also not explicitly disclosed by Abboud, it is for the same reasons as stated above with respect to the step of releasing the vacuum that Abboud also clearly fairly suggests the step of removing the vacuum cup from the bleeding site after releasing the vacuum, and it would also be obvious to one of ordinary skill in the art to modify the method of Abboud so as to include the step of removing the vacuum cup as claimed with a reasonable expectation of success to prevent inadvertent application of additional suction that could prompt an undesired cardiac event. (Page 904, 2nd col.)

With respect to **claim 3**: The bleeding site disclosed by Abboud is considered herein to be a rupture inasmuch as there is no laceration or wound site yet pooling of blood occurs, necessarily implying a rupture of blood vessels.

With respect to **claim 6**: Abboud discloses that the bleeding site can be further treated, e.g. by drug injection, to note the interaction of body receptors responsible for controlling cutaneous flow of blood. Abboud does not disclose but fairly suggests the step of releasing vacuum when blood flow has slowed. It is the examiner's position that because the injection occurs in the absence of vacuum and the effect is to slow the flow of blood, the injection, if it occurs during a procedure where vacuum is also applied, is conducted in the absence of said vacuum. Thus

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Abboud fairly suggests the vacuum is released when blood flow has slowed and the bleeding site can be further treated. The motivation to modify the method of Abboud so as to comprise the step of releasing the vacuum when blood flow has slowed is stated *supra* with respect to claim 1.

With respect to **claim 7**: Abboud discloses applying graded section only up to -40 mm Hg and discloses the monitoring of body response to the suction and its effect on blood flow to the bleeding site. Abboud discloses that the arterial baroreceptor reflex is invoked by excessive pooling caused by the amount of suction applied, and blood flow in the forearm slows as a result. Therefore while Abboud does not explicitly disclose that the vacuum is released immediately once the blood flow has slowed, Abboud certainly fairly suggests such a step of releasing the vacuum upon slowing the blood flow. It would therefore be obvious to one of ordinary skill in the art to modify the method of Abboud such that the vacuum is released immediately once the blood flow has slowed with a reasonable expectation of success to prevent further reaction prompted by the arteriobaroreceptor reflex that may cause an undesired cardiac event.

With respect to **claim 15**: Abboud discloses a method of addressing the flow of blood from a bodily tissue comprising: positioning the opening of a suction box (i.e. vacuum cup) over the bleeding site, wherein the vacuum cup necessarily includes an interior cavity; applying a vacuum to the interior cavity of the vacuum cup so as to cause one or both of pooling and slowing of the blood flow and maintaining the vacuum.

Abboud discloses applying graded section only up to -40 mm Hg and discloses the monitoring of body response to the suction and its effect on blood flow to the bleeding site.

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Abboud discloses that the arterial baroreceptor reflex is invoked by excessive pooling caused by the amount of suction applied, and blood flow in the forearm slows as a result. Therefore while Abboud does not explicitly disclose the step of releasing the vacuum upon said slowing of blood flow in the forearm, Abboud certainly fairly suggests such a step of releasing the vacuum upon slowing the blood flow. It would therefore be obvious to one of ordinary skill in the art to modify the method of Abboud so as to include the step of releasing the vacuum upon slowing the blood flow with a reasonable expectation of success to prevent further reaction prompted by the arteriobaroreceptor reflex that may cause an undesired cardiac event. Though the step of removing the cup/box from the bleeding site after releasing the vacuum is also not explicitly disclosed by Abboud, it is for the same reasons as stated above with respect to the step of releasing the vacuum that Abboud also clearly fairly suggests the step of removing the vacuum cup from the bodily tissue after releasing the vacuum, and it would also be obvious to one of ordinary skill in the art to modify the method of Abboud so as to include the step of removing the vacuum cup as claimed with a reasonable expectation of success to prevent inadvertent application of additional suction that could prompt an undesired cardiac event. (Page 904, 2nd col.)

With respect to **claim 16**: The bleeding site disclosed by Abboud is considered herein to be a rupture inasmuch as there is no laceration or wound site yet pooling of blood occurs, necessarily implying a rupture of blood vessels.

With respect to **claim 17**: The bleeding site disclosed by Abboud includes pooling of blood outside blood vessels, which is the definition of hematoma, thus the bleeding site disclosed by Abboud includes a site of hematoma.

With respect to **claims 18-23**: Abboud does not disclose that the bleeding site includes a site of laceration, site of injury, site of surgery, an incision site or a site accessed via a laparoscope. However, since the method meets all of the limitations of claim 1 as to a method of slowing the flow of blood, it is the examiner's position that the method as practiced is fully capable of slowing the flow of blood in a laceration, site of injury, site of surgery, an incision site or a site accessed via a laparoscope, and it would be obvious to one of ordinary skill in the art to practice the method disclosed by Abboud wherein the bleeding site is a laceration with a reasonable expectation of success to slow the flow of blood and prevent a cardiac event.

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abboud in view of Thompson et al (U.S. Patent No. 1,460,927).

With respect to **claim 4**: Abboud does not disclose that the vacuum cup is formed of a material selected from the group consisting of rubber, plastic, silastic, silicone, and metal. Thompson discloses a rubber vacuum cup intended for use on a human patient. Since this rubber vacuum cup is suitable for use on a human patient, it is suitable for use in the method of Abboud. Rubber is flexible and biocompatible and thus it would be obvious to one of ordinary skill in the art to modify the method of Abboud such that the vacuum cup is made of rubber as disclosed by Thompson to provide a flexible cup that is also biocompatible and thus suitable for use on a human patient.

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abboud in view of Hill (U.S. Patent No. 5,643,183).

With respect to **claim 5**: Abboud does not disclose that the vacuum cup is formed of transparent polyethylene material. Hill discloses a waterproof transparent polyethylene cover for a wound bandage and discloses that using transparent polyethylene allows the user to see if fluids are leaking in or out of the cover and that use of this material allows reuse of the cover. ('183, Col. 3, lines 1-7) Therefore, it would be obvious to one of ordinary skill in the art to modify the method of Abboud such that the cup is formed of transparent polyethylene as disclosed by Hill to allow visual detection of leakage and reuse of the cup/cover.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Melanie J Hand/
Primary Examiner, Art Unit 3761